

How to designate PT providers and products

The proficiency testing (PT) products listed meet the New York State (NYS) PT requirements. The Category Specific Help link provides information on NYS mandated analytes that require PT participation. Please consult the PT provider's website and catalog to determine that you are designating an appropriate product for your methodology and instrumentation, and to find additional important details.

Please contact the PT Administration Group by email at PTAdmin@health.ny.gov with any questions regarding PT product enrollment and/or designation.

Note that you can save your work at any time. The information you entered will still be available if you need to come back to the page, even after logging out.

Login to eCLEP through the Health Commerce System (HCS) home page.

PLEASE LOGIN TO BEGIN USING THE HEALTH COMMERCE SYSTEM (HCS)



User ID

Password



Forgot Your [User ID](#) or [Password](#) Remember User ID


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Don't Have An Account? [Sign Up Here](#)

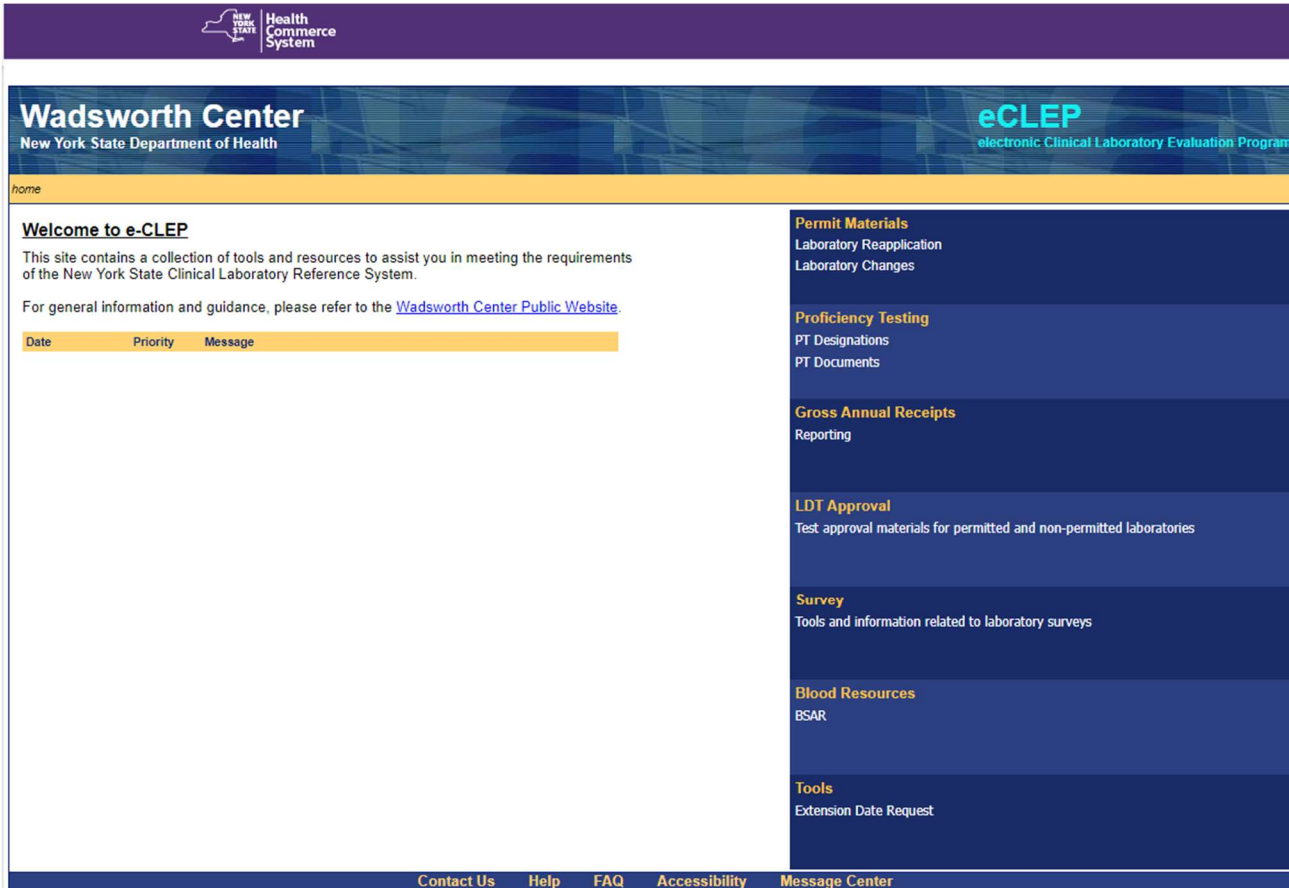
On the HCS home page, under **My Applications**, select **eCLEP**.

My Applications

Acronyms & Abbreviations	
eCLEP	
Emergency Contacts	
ServNY	

Refresh My Applications List


On the **Welcome to e-CLEP** home page, under **Proficiency Testing**, select **PT Designations**.



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New York State Department of Health

eCLEP
electronic Clinical Laboratory Evaluation Program

home

Welcome to e-CLEP
This site contains a collection of tools and resources to assist you in meeting the requirements of the New York State Clinical Laboratory Reference System.
For general information and guidance, please refer to the [Wadsworth Center Public Website](#).

Date	Priority	Message
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Permit Materials
Laboratory Reapplication
Laboratory Changes

Proficiency Testing
PT Designations
PT Documents

Gross Annual Receipts
Reporting

LDT Approval
Test approval materials for permitted and non-permitted laboratories

Survey
Tools and information related to laboratory surveys

Blood Resources
BSAR

Tools
Extension Date Request

[Contact Us](#) [Help](#) [FAQ](#) [Accessibility](#) [Message Center](#)

Alternately, on the **Proficiency Testing (PT) – Home** page, select **PT Designations**.

The screenshot shows the Wadsworth Center eCLEP website. The header includes the Wadsworth Center logo and the eCLEP (electronic Clinical Laboratory Evaluation Program) logo. A navigation bar contains tabs for Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, Blood Resources, and Tools. The Proficiency Testing tab is active. On the left, there are links for PT Home, PT Designations, and PT Documents. The main content area is titled "Proficiency Testing (PT) - Home" and contains instructions on how to use the links for PT Designations and PT Documents. The footer includes links for Contact Us, Help, FAQ, Accessibility, and Message Center.

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home > proficiency testing [Select Facility](#)

[Permit Materials](#) [Proficiency Testing](#) [Gross Annual Receipts](#) [LDT Approval](#) [Survey](#) [Blood Resources](#) [Tools](#)

[PT Home](#)
[PT Designations](#)
[PT Documents](#)

Proficiency Testing (PT) - Home

Use the links below to designate PT providers or to view PT related documents.

- **PT Designations**, when open, is used to notify CLEP of both the PT Provider(s) and product(s) the laboratory intends to enroll with for all tests/analytes offered that are either listed in CMS 42 CFR 493 subpart I (CLIA subpart I) OR defined by NYS as requiring PT (collectively, NYS mandated PT analytes).
- **PT Documents** include important time-sensitive information for your laboratory including verification of PT enrollment and PT participation issues, and PT performance.

[PT Designations](#) [PT Documents](#)

[Contact Us](#) [Help](#) [FAQ](#) [Accessibility](#) [Message Center](#)

Either choice will bring you to the **Proficiency Testing (PT) – Designations** home page.

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home > proficiency testing > pt designations [Select Facility](#)

[Permit Materials](#) [Proficiency Testing](#) [Gross Annual Receipts](#) [LDT Approval](#) [Survey](#) [Blood Resources](#) [Tools](#)

[PT Home](#)
[Instructions](#)
[Category Specific Help](#)
[FAQs](#)
[Browser Issues](#)

Designation Steps
[Step 1. Indicate Tests Offered on NYS Specimens](#)
[Step 2. Designate PT provider and product](#)
[Step 3. View designations](#)
[Step 4. Submit designations](#)

PFI: **Name:**

Proficiency Testing (PT) - Designations

Use the links at the left to begin or continue the designation process, view instructions, or find additional help regarding specific PT products.

Laboratories seeking or holding a New York State (NYS) clinical laboratory permit through the Clinical Laboratory Evaluation Program (CLEP) must enroll in proficiency testing (PT) as defined by NYS (NYS mandated PT). NYS mandated PT includes all tests/analytes offered by the laboratory that are either listed in CMS 42 CFR 493 subpart I (CLIA subpart I) OR defined by NYS as requiring PT.

In addition, each laboratory must designate the PT products that will be used to satisfy these PT requirements. Laboratories currently holding a NYS CLEP permit or those in applied status for a permit must designate these PT products via this website. This process applies ONLY to your laboratory's PRIMARY test method.

This website lists tests that require PT (a.k.a NYS mandated PT analytes) and prescreened PT products offered by the CMS-approved PT Providers that have been screened by CLEP to identify those that meet New York State PT requirements for NYS mandated PT analytes. **Note that ONLY those PT products listed are acceptable.**

For each test, your laboratory must indicate whether the test is offered on NYS specimens and, if so, indicate a PT Provider and product. You must click on the links at the left side of the page to progress through the process. You must click "submit" on the final page before the notification period ends.

- **Failure** to designate and submit your planned enrollment may result in citation under NYS Clinical Laboratory Standard of Practice **Proficiency Testing Standard of Practice 1 (PT S1): Enrollment, Department Notification and Participation.**
- Laboratories are required to authorize their PT Providers to submit PT results to NYS. **Be sure to provide the PT Provider with the NYS PFI number.** If your PT Provider requests a contact name and fax number, please indicate Beverly Rauch at fax number (518) 408-8666. **Failure** to authorize release of PT results to NYS may result in citation under NYS Clinical Laboratory Standard of Practice **Proficiency Testing Standard of Practice 2 (PT S2): Authorized Release of Proficiency Testing Results.**
- CLEP will compare your planned enrollment to the PT scores we receive from the PT Providers in January. **Failure** to participate in the PT products selected here may result in citation under NYS Clinical Laboratory Standard of Practice **Proficiency Testing Standard of Practice 1 (PT S1): Enrollment, Department Notification and Participation.**
- Laboratories must participate with their chosen provider(s) for the entire calendar year before designating a different program.

NOTE: The laboratory must comply with **Proficiency Testing Standards of Practice 3 (PT S3): Alternative to Proficiency Testing** for all tests not subject to NYS PT requirements (e.g., those not indicated as a NYS mandated PT analyte).

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Step 1. Indicate Tests Offered on NYS Specimens

Click on “Step. 1 Indicate Tests Offered on NYS Specimens”

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home > proficiency testing > test selection Select Facility

Permit Materials | Proficiency Testing | Gross Annual Receipts | LDT Approval | Survey | Blood Resources | Tools

[PT Home](#)
[Instructions](#)
[Category Specific Help](#)
[FAQs](#)
[Browser Issues](#)

Designation Steps

- Step 1. Indicate Tests Offered on NYS Specimens
- Step 2. Designate PT provider and product
- Step 3. View designations
- Step 4. Submit designations

Indicate Tests Offered on NYS Specimens

Laboratories applying for or holding a New York State (NYS) comprehensive clinical laboratory permit through the Clinical Laboratory Evaluation Program (CLEP) must enroll in proficiency testing (PT) as defined by NYS (NYS mandated PT). NYS mandated PT includes all tests/analytes offered by the laboratory that are either listed in CMS 42 CFR 493 subpart I (CLIA subpart I) OR defined by NYS as requiring PT.

Laboratories offering these tests on NYS specimens must designate which PT provider and survey they will use to satisfy these requirements for the upcoming calendar year. For a list of NYS-acceptable PT providers and surveys, please visit:
<https://www.wadsworth.org/regulatory/clep/pt/provider-search>.

Categories Requiring PT:

- Bacteriology
- Blood pH and Gases
- Clinical Chemistry
- Diagnostic Immunology - Diagnostic Services Serology
- Diagnostic Immunology - Donor Services Serology
- Hematology
- Immunohematology
- Mycobacteriology
- Mycology
- Oncology - Soluble Tumor Markers
- Parasitology
- Ther. Sub. Mon./Quant. Tox.
- Toxicology - Blood Lead-ASV Using Screen Printed Sensors
- Toxicology - Blood Lead-Comprehensive
- Virology

Show 40 entries

Name	Status

Showing 0 to 0 of 0 entries (filtered from 112 total entries)

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Only categories your laboratory holds or has requested (is in applied status for) that contain analytes requiring PT participation will appear in the drop-down menu on the page labeled “Indicate tests Offered on NYS Specimens”.

For each category in the drop-down menu select “Test Offered” or “Test Not Offered” for each test/analyte in the list. Select “Test Offered” for a test/analyte even if your laboratory has temporarily suspended testing.

The screenshot displays the eCLEP (electronic Clinical Laboratory Evaluation Program) interface for Wadsworth Center, New York State Department of Health. The page is titled "Indicate Tests Offered on NYS Specimens" and is part of a multi-step process for designating tests. The left sidebar contains navigation links for "PT Home", "Instructions", "Category Specific Help", "FAQs", "Browser Issues", and "Designation Steps". The "Designation Steps" section lists four steps, with the first step, "Step 1. Indicate Tests Offered on NYS Specimens", currently selected. The main content area includes a "Name:" field, a "PFI:" field, and a "Categories Requiring PT:" dropdown menu set to "Toxicology - Blood Lead-Comprehensive". Below this, there is a "Help/Instructions" section for "Toxicology - Blood Lead-Comprehensive" with a bulleted list of requirements: a minimum of five samples per testing event, three shipments per year, and samples for all CLIA subpart I analytes as listed in the Category Specific Help document. A "Category Specific Help" link is provided. At the bottom of the page, there is a "Show 40 entries" dropdown, a search field, a table with columns "Name" and "Test Status", and a "Showing 1 to 1 of 1 entries (filtered from 16 total entries)" message. The "Test Status" for the "blood lead" entry is "Test Offered". A "Save" button and a "Clear" button are located at the bottom left of the page.

Be sure to save before moving to the next category.

You must save your work for EACH permit category by clicking the ‘Save’ button at the bottom of the page before choosing a different permit category or clicking a different link. Any unsaved data will be lost.

Step 2. Designate PT provider and product

Click on “Step 2. Designate PT provider and product”

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home > proficiency testing > provider product Select Facility

Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Blood Resources Tools

[PT Home](#)
[Instructions](#)
[Category Specific Help](#)
[FAQs](#)
[Browser Issues](#)

Designation Steps

- [Step 1. Indicate Tests Offered on NYS Specimens](#)
- Step 2. Designate PT provider and product**
- [Step 3. View designations](#)
- [Step 4. Submit designations](#)

PFI: **Name:**

Designate PT provider and product

Next, please choose a PT provider and PT product. Approved PT products must include at least 5 samples provided 3 times per year (except for Mycobacteriology, which is 2 times per year). This requirement also applies to laboratories offering these tests using waived kits/devices. For a list of NYS-acceptable PT providers and products, please visit <https://www.wadsworth.org/regulatory/clep/pt/provider-search>.

Categories Requiring PT:

Show entries Search:

PT Designations - PRIMARY METHOD

Test Name	Provider	Product
blood lead	WI State Laboratory of Hygiene	Blood Lead - 01080

Showing 1 to 1 of 1 entries 1 row selected

*Your PT Provider will not be saved unless you have also chosen a product.

[Contact Us](#) [Help](#) [FAQ](#) [Accessibility](#) [Message Center](#)

Select a category from the drop-down menu.

- The message 'no data' means that your laboratory has selected "Test Not Offered" for all tests that require PT participation in this permit category.
- Select your PT provider from the 'Provider' drop-down menu for each "Test Offered" from Step 1.
- The 'Product' drop-down menu will automatically populate with appropriate product(s) offered by that provider.
- Select the PT product in which you have enrolled or intend to enroll for each "Test Offered".
- Click the 'Save' button for each permit category before selecting another category or leaving this page.

NOTES

- Designate PT ONLY for your primary method. Your laboratory may enroll in additional PT for secondary methods for these tests. Do not designate them here.
- While you may order additional PT samples for certain surveys to assess secondary methods, it is critical that the additional materials and secondary method(s) be tested AFTER the event deadline has passed.
- PT for waived testing performed in a comprehensive clinical laboratory regulated by CLEP must comply with CLIA requirements (generally, five PT samples per event and three events per year). PT products that DO NOT meet these criteria are omitted from the drop-down menus.
- Enrolling in surveys omitted from the drop-down menus will result in citation under New York State Clinical Laboratory Standard **Proficiency Testing Standard of Practice (PT S1): Enrollment, Department Notification and Participation.**

Repeat Steps 1 and 2 for all permit categories

Step 3. View Designations

Click on “Step 3. View designations”

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home > proficiency testing > pending designations [Select Facility](#)

Permit Materials **Proficiency Testing** **Gross Annual Receipts** **LDT Approval** **Survey** **Blood Resources** **Tools**

[PT Home](#)
[Instructions](#)
[Category Specific Help](#)
[FAQs](#)
[Browser Issues](#)

Designation Steps
[Step 1. Indicate Tests Offered on NYS Specimens](#)
[Step 2. Designate PT provider and product](#)
Step 3. View designations
[Step 4. Submit designations](#)

PFI: **Name:** |

View Designations

A total of 4 record(s) have been modified. Listed below are all the "tests offered" and "tests not offered" by your laboratory. The "tests offered" include your PT product designation(s). The tests with a checkmark (✓) were modified since the last submission. Tests without a checkmark are persistent data from previous designations.

Tests Offered

Category	Test	Provider	Product
Toxicology - Blood Lead-Comprehensive	blood lead	WI State Laboratory of Hygiene	Blood Lead - 01080

[Download Tests Offered](#)

Tests Not Offered

Category	Test
Category	Test

[Download Tests Not Offered](#)

[Contact Us](#) [Help](#) [FAQ](#) [Accessibility](#) [Message Center](#)

This page summarizes the information you designated and any records on PT provider and/or product on file.

- Provider and product designations include both those from previous year(s) and those modified in Step 2. Modified records, both additions (new “Test Offered”) and deletions (“Test Not Offered”), are denoted by a ‘+’ in the chart.
- Please review and make any necessary changes before submitting. Changes can be made by returning to Steps 1 and 2.
- Print this page for your records.
- Alternately, use the “Download” buttons to save a csv file to your computer.

Step 4. Submit Designations

Click on “Step 4. Submit Designations”

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home > proficiency testing > pt submission Select Facility

[Permit Materials](#) [Proficiency Testing](#) [Gross Annual Receipts](#) [LDT Approval](#) [Survey](#) [Blood Resources](#) [Tools](#)

[PT Home](#)

[Instructions](#)

[Category Specific Help](#)

[FAQs](#)

[Browser Issues](#)

Designation Steps

[Step 1. Indicate Tests Offered on NYS Specimens](#)

[Step 2. Designate PT provider and product](#)

[Step 3. View designations](#)

Step 4. Submit designations

Submit designations

PFI: **Name:**

Unassigned Tests / Tests Offered without an assigned product

Additional information is required for all tests listed below. You must complete the information required in order to submit designations. Review steps 1 and 2 to assure that all information is included.

Category	Test Name
Virology	Culture ID of viruses
	ID of herpes simplex virus (HSV) and related viruses
	Molecular ID of gastrointestinal viruses
	Molecular ID of meningitis pathogens (viral)
	Molecular ID of respiratory viruses

Attestation

Please read the following attestation carefully. If you agree, signify by clicking the checkbox (* required), then click 'Submit'.

I understand that signing and submitting this record in this fashion is the legal equivalent of having placed my handwritten signature on the submitted record and this affirmation. I understand and agree that by electronically signing and submitting this record in this fashion I am affirming to the truth of the information contained therein.

I, the laboratory director or delegated submitter, attest that my laboratory has enrolled or will enroll in the PT surveys designated here. I understand that these designations are binding for the coming calendar year and that failure to enroll and participate in these surveys for these analytes may result in regulatory sanctions. I further understand that satisfactory PT performance is required to maintain my laboratory's CLEP permit.

I have read, and agree with, the above attestation.

Comment

If you would like to provide a comment, please do so below: (500 characters max) Characters Remaining: 500

[Contact Us](#) [Help](#) [FAQ](#) [Accessibility](#) [Message Center](#)

- If there are tests listed on this page, you either did not select a test status in Step 1 or you did not designate a PT provider and/or product in Step 2, or both. Return to the steps to enter the required information.
- When there are no tests listed on this page, read the **Attestation** statement, and then check the box to indicate your agreement.
- Once you click the 'Submit' button to complete the PT designation process you will no longer be able to make changes.